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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,360	12/15/2003	Adam P. Dicker	0325991-54740	6009

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DAVID S. RESNICK
100 SUMMER STREET
NIXON PEABODY LLP
BOSTON, MA 02110-2131

EXAMINER	
KWON, BRIAN YONG S	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/737,360	DICKER ET AL.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-18* is/are pending in the application.

4a) Of the above claim(s) *2-4,11,15 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,7-10,12-14,17 and 18* is/are rejected.

7)☒ Claim(s) *13 and 14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Acknowledgment is made of applicant's filing of Argument filed 01/29/2007. By the amendment, claim 6 has been cancelled; claims 1, 10 and 13 have been amended; and claims 17 and 18 have been newly added. Claims 1, 5, 7-10, 12-14 and 17-18 are currently pending for prosecution on the merits of the case.

2. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

3. Applicant's arguments with respect to claims 1, 5-10 and 12-14 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment narrowing the scope of the invention by reciting "wherein the proliferative disease is a solid tumor" (claim 1), namely "glioma" (claim 10) and "lung carcinoma" (claim 17), namely "non-small cell lung carcinoma" (claim 18) necessitates a new ground of the rejection in this Office Action.

Claim Objections

4. The claims 13 and 14 are objected of being redundant in describing identical compounds. For example, Brand name drugs, Reopro (Brand name), Arixtra, Novastan, and Streptas, refer to the same compound, abciximab, fondaparinux sodium, argatroban and streptokinase, respectively.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13 and 14 contain the trademark/trade name Plavix, Reopro, Arixtra, Novastan, Steptase, Ticlid, Retavase, Activase, TNKase, Integrilin, Innohep and etc... Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe clopidogrel, abciximab, fondaparinux sodium, argatroban, streptokinase, ticlopidine, reteplase, alteplase, teneteplase, eptifibatide, tinzaparin and etc... and, accordingly, the identification/description is indefinite.

This rejection could be overcome by amending claims 13 and 14 to recite "clopidogrel bisulfate (Plavix), abciximab (Reopro), fondaparinu sodium (Arixtra), argatroban (Novastan)..." or "clopidogrel bisulfate (Plavix)" respectively.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 5, 7, 8, 10, 13 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by EL-Naggar et al. (USP 6908907).

EL-Naggar teaches a use of a composition comprising anti-platelet agent such as GPIIB/IIIa antagonist (i.e., abciximab, tirofiban, orbofiban, sibrafiban, etc...) and anticoagulant (i.e., dalteparin and tinazaparin) in combination with radiation therapy (abstract; column 1, lines 7-23; column 8, lines 23-41; column 9, lines 26-34) for the treatment of cancer associated with metastasis, angiogenesis, tumor growth and thrombosis including solid tumor (e.g., lung, neuroblastomas, glioblastoma, etc...) wherein said combination is administered in sequentially or separately or concurrently (Table 2 and column 12, lines 23-28).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over EL-Naggar et al. (USP 6908907).

The teaching of EL-Naggar has been discussed in above 35 USC 102(e) rejection.

The teaching of El-Naggar differs from the claimed invention in "said anti-platelet agent is administered first".

However, those of ordinary skill in the art would have been readily optimized effective concurrent administration regimens as determined by good medical practice and the clinical condition of the individual patient. Determination of the appropriate order of administration

regimen for treatment involving each of the above mentioned formulations is routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of the sequential (separate) or concurrent administration disclosed in the El-Naggar.

Generally, differences in time will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such time difference is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable time ranges by routine experimentation.

8. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over EL-Naggar et al. (USP 6908907), and further in view of Nichtberger (USP 6136804).

The teaching of EL-Naggar has been discussed in above 35 USC 102(e) rejection.

Nichberger is being supplied as a supplemental reference to demonstrate the use of clopidogrel or clopidogrel bisulfate (Plavix) as functional equivalent to GIIb/IIIa receptor antagonist (column 17, lines 56-58 and column 23, line 5).

The teaching of El-Naggar differs from the claimed invention in (i) the use of specific anti-platelet agent such as clopidogrel or clopidogrel bisulfate (Plavix). To incorporate such teaching into the teaching of EL-Naggar, would have been obvious in view of Nichberger who teaches the use of clopidogrel or clopidogrel bisulfate (Plavix) as functional equivalent to GIIb/IIIa receptor antagonist.

One having ordinary skilled in the art would have found it obvious to substitute said GIIb/IIIa receptor antagonist with clopidogrel or clopidogrel bisulfate because these agents were art-recognized functional equivalents at the time of the invention was made in the

pharmaceutical art. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

9. Claims 12 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over EL-Naggar et al. (USP 6908907), and further in view of Hallahan et al. (USP 5962424) and Stewart et al. (USP 6887474).

The teaching of El-Naggar has been discussed in above 35 USC 102(e) rejection.

Hallahan is being supplied as supplemental reference to demonstrate routine knowledge in using ionizing radiation for the treatment of solid tumor (abstract; column 2, line 55; column 5, line 66).

Stewart is being supplied as supplemental reference to demonstrate routine knowledge in using anti-platelet drug (e.g., anti-GPIIb/IIIa agent and clopidogrel) in treating solid tumor masses including small cell lung carcinoma (column 7, lines 6-13; column 4, lines 12-18; column 11, line 39; column 13, line 67)

The teaching of El-Naggar differs from the claimed invention in (ii) the use of ionizing radiation and (iii) the treatment of non-small cell lung carcinoma.

Above references in combination make clear that ionizing radiation therapy is routinely utilized in the treatment of solid tumor and solid tumor such as lung carcinoma, particularly non-small cell lung carcinoma, is routinely managed by radiation therapy as well as anti-platelet agent.

Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. No Claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon
Patent Examiner
AU 1614